NOV 1 3 2002

F: 510(k) Summary

K 023492

October 16, 2002

Company:	Gyrus Medical, Inc. 6655Wedgwood Road Maple Grove, MN Tel. No. (763) 416-3000 FAX. No. (763) 416-3070
Contact:	Frederick G. Mades Regulatory Affairs Manager
Common/Usual Name:	Electrosurgical Instruments
Classification Name:	Electrosurgical Cutting and Coagulation Device And Accessories (21 CFR 878.4400)
Proprietary Name:	Everest Bipolar Cutting Forceps and Gyrus Bipolar Cutting Forceps

This device is a Class II medical device. The Bipolar Cutting Forceps is a modification to the predicate devices cleared under K904993. The Bipolar Cutting Forceps is similar in construction (with the exception of shaft length) and in component materials when compared to the predicate device. The forceps jaws are electrically isolated from each other enabling one jaw to act as a return electrode, eliminating the need for a return pad. To transect tissue a cutting blade is actuated and moves between the electrode jaws. The modification has not altered the fundamental technology of the predicate devices. The intended use, electrosurgical coagulation, grasping, dissection and mechanical cutting of tissue during surgical procedures is identical to the predicate devices cleared under K904993. The energy source, bipolar electrosurgical energy, is the same energy type as used for the predicate devices.

In conclusion, as the design, materials of construction, function and intended use of the modified bipolar cutting forceps is similar to that of the predicate devices currently cleared, Gyrus Medical Inc. believes that no new issues of safety and effectiveness are raised and that the submitted device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Gyrus Medical, Inc.
Frederick G. Mades
Regulatory Affairs Manager
6655 Wedgwood Road, # 105
Maple Grove, Minnesota 55311-3602

Re: K023492
Trade/Device Name: Everest Bipolar Cutting Forceps and Gyrus Bipolar Cutting
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories;
Regulatory Class: Class II
Product Code: GEI
Dated: October 16, 2002
Received: October 18, 2002

Dear Mr. Mades:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023492

Device Name: Everest Bipolar Cutting Forceps and Gyrus Bipolar Cutting Forceps

Indications for Use:

Electrosurgical coagulation, mechanical cutting, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.

Prescription Use ✓

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Miriam C Provost

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K023492